REMARKS

Claims 9-23 are pending. Claims 9-23 are amended herein. Support for the amendments are found throughout the specification at, *inter alia*, page 64, line 35 to 70, line 12. It is believed that no new matter has been added. No claim is allowed.

Examiner Interview Summary

Examiners Qian and Yucel participated in an interview with the undersigned on August 25, 2005. Applicants appreciate the opportunity to speak with Examiners Qian and Yucel. The discussion related to the scope and substance of the outstanding rejections and the evidence of record. Various aspects of the evidence were discussed. No agreement was reached on the claims.

Rejection under 35 U.S.C. § 101

Claims 9-23 were rejected under 35 U.S.C. § 101 because the claimed compositions allegedly are not supported by either a credible, substantial and specific asserted utility or a well established utility for reasons of record. Briefly, the Examiner asserts that the specification fails to which specific pathway in any specific cell type that leads to a specific disease. Applicants respectfully traverse this rejection for reasons of record as well as those discussed below.

Applicants again respectfully submit that the specification easily fulfills the utility requirement pursuant to 35 U.S.C. § 101. First, the specification discloses a number of specific utilities for CD200R including functioning in specific conditions such as multiple sclerosis, rheumatoid arthritis, and autoimmune disease. Thus, an antibody to CD200R has utility as a therapeutic or a diagnostic agent at a minimum. The claimed compositions have a "real world" function. Second, the disclosed utility is substantial. An antibody specific for CD200R that can potentially treat or diagnose diseases such as inflammation, multiple sclerosis, rheumatoid arthritis, and autoimmune disease is a real world use of the antibody to CD200R. Finally, the disclosed utility is credible to one of ordinary skill in the art. Applicants previously provided numerous publications demonstrating the role of CD200R *in vitro* and in animal models recognized by skilled artisans as predictive of human disease and support the specific utilities disclosed in the

specification. Thus, the specification fulfills the utility requirement by setting forth useful and practical utilities that are credible and immediately apparent to the skilled artisan.

Contrary to the assertion of the Examiner, the identification of a specific pathway is not required to demonstrate utility. The specification provides sufficient detail to provide meet the utility requirement by indicating the cells expressing CD200R, *i.e.*, those of the myeloid lineage, in specific diseases, *i.e.*, multiple sclerosis, rheumatoid arthritis, and inflammatory conditions, and disclosing the inhibition of the activity of CD200R to treat these conditions. *See, e.g.,* the specification at page 75, lines 7-29. The objective evidence supports these specific disclosures. Nothing more is required as breadth of application of the claimed compositions fails to render a utility non-specific or non-substantial. Moreover, a specific teaching that CD200R *results* in a particular disease is not required. A disease may be modulated by altering the function of a cell expressing a particular receptor. In the instant application, it is expressly disclose to inhibit the function of CD200R to modulate the specific diseases listed. Applicants respectfully that a disclosed utility for the claimed subject matter satisfies the utility requirement under § 101 absent evidence which would cast doubt on the objective truth of the disclosed utility. M.P.E.P. § 2107.02 (III)(A). There is no legal requirement that the disclosed utility must be supported by conclusive experimental data. According to the M.P.E.P.,

> [a]s a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

MPEP § 2107.02 (III) (A) (emphasis original). Furthermore, an applicant is not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or "as a matter of statistical certainty." *See* M.P.E.P. § 2107.02 (VII). An applicant is only required to provide evidence if, when considered as a whole, leads the skilled artisan to conclude that the asserted utility is more likely than not true. *See* M.P.E.P. § 2107.03 (II).

In view of the above, Applicants respectfully request the basis of this rejection be removed.

Rejections under 35 U.S.C. § 112, first paragraph - written description

Claims 9-23 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that the claimed binding compounds may not even bind SEQ ID NO:20 itself. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the specification adequately describes the claimed compositions. First, the claims are directed to antibodies or an antigen-binding fragment thereof. The genus of antibodies and antigen binding fragments are described in detail at, *inter alia*, page 64, line 35 to 70, line 12. Applicants are somewhat unclear why the Examiner believes that a compound that does not bind SEQ ID NO:20 would fall within the scope of the claim. The plain language of the claim is drawn to compositions that bind OX2R (or CD200R) via a binding site from an antibody that specifically binds SEQ ID NO:20 or a fragment thereof. Given the plain language and that state of the art regarding antibodies (as discussed in previous responses), the specification provides adequate description of the claimed CD200R-binding antibodies and antigen-binding fragments thereof.

In view of the above, Applicants respectfully request the basis of this rejection be removed.

Rejections under 35 U.S.C. § 112, first paragraph - enablement

Claims 9-23 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner asserts that it is unclear whether the skilled artisan can make compounds other than antibodies or binding compounds to polypeptides comprising SEQ ID NO:20. Applicants respectfully traverse this rejection.

Applicants submit that the specification provides reasonable enablement for the claimed compounds. The specification describes how to make and use the antibodies and antigen-binding fragments thereof at, *inter alia*, page 64, line 35 to 70, line 12.

In view of the above, Applicants respectfully request the basis of this rejection be removed.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 13 and 14 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. According to the Examiner, the recitation of "the attached to a solid substrate" renders the claim indefinite because it is unclear what is attached to the solid substrate. Applicants traverse this rejection.

As a preliminary matter, Applicants regret overlooking this rejection and appreciate the opportunity to address it in this response.

Claim 13 is amended herein to clarify that it is the OX2R-binding antibody or antigen binding fragment thereof that is attached to the solid substrate. Thus, the claims as amended is sufficiently definite to apprise the skilled artisan of the scope of the claimed compositions.

In view of the above, Applicants respectfully request the basis of this rejection be removed.

Objection to the Claims

Claim 22 is objected to because of alleged informalities. The Examiner asserts that "some fragment" should be made plural. Applicants traverse this objection.

Claim 22 is amended herein to clarify the terminology used for the CD200R fragment as "a" fragment. It is believed that this addresses the grammatical informality as noted by the Examiner. Applicants appreciate the careful analysis of the claims performed by the Examiner.

In view of the above, Applicants respectfully request this objection be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. Alternatively, the Examiner is requested to enter the amendments to reduce the issues that will be the subject of appeal.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 15, 2005

Respectfully submitted,

By _____

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